

### **REMARKS**

Reconsideration of this application in light of the above amendments and the following remarks is respectfully requested.

#### **I. Status of the Claims**

Claims 1, 24-34, 42, 44, 52, 64, 65, 67, 69 and 70 have been canceled without prejudice. Claim 59 has been amended for clarity and to specify that the drug substance is tacrolimus. Claims 2-23, 36, 39-41, 43, 45-51, 53-57, and 66 have been amended for clarity and to depend from claim 59. Claims 71-90 have been added. Support for these amendments can be found at, for example, paragraphs 19, 50, 53, 56, 71, 73, 87, 96 and 214, Example 2, and Figure 2 of the published version of this application (US 2007/0122482). Claims 2-23, 36, 39-41, 43, 45-51, 53-57, 59, 66, and 71-90 will be pending upon entry of this amendment. No new matter has been added by way of this amendment.

#### **II. Objection to the Specification**

The specification has been objected to for reciting the trademark names for drugs on pages 26 and 27 of the specification without reciting their generic names. The specification has been amended to include the generic names for these drugs. Accordingly, Applicants respectfully request withdrawal of this objection.

The Examiner noted a typographical error in the trademark XENICAL®. This error has been correct.

### III. Claim Objection

Claim 24 has been objected to by the Examiner. As this claim has been canceled (without prejudice), this objection is moot.

### IV. Indefiniteness Rejection

Claims 1–34, 36, 39–57, 59, 64–67, 69 and 70 have been rejected as indefinite. The Examiner contends that it is unclear how in step iii), the one or more release-rate modifiers are added by dry mixing. The Examiner argues that mixing “is a process in which ingredients already present are manipulated to incorporate any newly added ingredients into those already present” (Office Action, p. 7). Thus, according to the Examiner, “it does not seem possible for an ingredient to be added by dry mixing” (*id.*).

Applicants note that claims 59 and 86 are the only independent claims at issue. Claim 59 calls for “dry mixing” in step (v).

The term “mix” is defined as “combine; blend; put together,” or “merge, unite, ... mingle” (*see* Exhibit 1, submitted herewith). Step (v), therefore, describes how the release-rate modifier is combined, blended or merged into the composition (*i.e.*, by dry mixing).

The Examiner argues that the claims are unclear because “step (iv) requires mechanically working the second composition and then applying it to the first composition, which seems to overlap with what is occurring in step (i)” (Office Action, p. 7).

Claims 59 and 86 do not call for mechanically working the *second* composition. Claim 59 calls for mechanically working the *resulting* composition. Therefore, this rejection does not apply to the pending claims.

For the reasons above, Applicants respectfully request withdrawal of this rejection.

**V. Obviousness Rejections**

Claims 1-34, 36, 39-57, 59, 64-67, 69 and 70 have been rejected as obvious over WO 03/004001 ("WO '001").

The present claims call for a tacrolimus composition. WO '001 does not disclose tacrolimus. Therefore, a *prima facie* case of obviousness has not been established.

Furthermore, WO '001 does not disclose a tacrolimus composition containing hydroxypropyl methylcellulose in a sufficient amount to provide modified release of the tacrolimus (as recited in claims 74-76). Nor does WO '001 disclose a tacrolimus composition containing polyethylene glycol, poloxamer, and hydroxypropyl methylcellulose (as recited in claims 75 and 76).

For at least these reasons, Applicants respectfully request withdrawal of this rejection.

**VI. Double Patenting Rejections**

Claims 1–3, 5–8, 11–14, 16–18, 22–24, 26, 27, 36, 43, 45, 47, 48, 53 and 67 are rejected for obviousness-type double patenting over claims 1–18, 33–36, 38–42 and 44 of U.S. Patent No. 7,217,431 in view of Tousey. U.S. Patent No. 7,217,431 is the national stage entry of WO 03/004001 (“WO ‘001”). Tousey is a review of various granulation processes, and does not disclose or suggest a tacrolimus composition. Accordingly, Tousey does not cure the deficiencies of U.S. Patent No. 7,217,431. Accordingly, Applicants respectfully request withdrawal of this rejection for at least the reasons set forth above.

Claims 1-3, 5-8, 11-14, 16-18, 22-24, 26, 27, 36, 43, 45, 47, 48, 53 and 67 are provisionally rejected for obviousness-type double patenting over claims 57-77, 90-95, 99-105 and 107-116 of co-pending U.S. Patent Application No. 11/711,965 in view of Tousey. U.S. 11/711,965 is a continuation of U.S. Patent No. 7,217,431, which is the national stage entry of WO ‘001. As stated above, Tousey does not cure the deficiencies of WO ‘001. Accordingly, Applicants respectfully request withdrawal of this rejection for at least the reasons set forth above.

**CONCLUSION**

Based on the above amendments and arguments, the subsisting claims are believed to be in condition for allowance, and such action is earnestly solicited. If there are remaining issues that the Examiner believes could be addressed by conducting an interview or entering an Examiner’s Amendment, the Examiner is cordially invited to contact the undersigned agent to discuss such issues.

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Respectfully submitted,

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- Exhibit 1 – Definition of “mix” (4 pages)

THE  
Pocket  
Oxford  
Dictionary  
and  
Thesaurus

*American Edition*

Edited by  
Frank R. Abate

**Oxford University Press**  
New York    Oxford

Oxford University Press

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